# Exhibit I

Case 3:06-cy-03072-MWB Document 2-1 Filed 11/03/2006 Page 1 of 23

Dutton, Braun, Staack & Hellman, P.L.C. 3151 Brockway Road P.O. Box 810 Waterloo, Iowa 50704-0810 James H. Cook (AT0001622) 319-234-4471 - Office 319-234-8029 - Fax E-Mail: cooki@wloolaw.com

#### UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF IOWA CENTRAL DIVISION

BRIAN COLLINS, Plaintiff, CASE NO. 3:06-cv-03072-MWB ٧. BIOMEDICAL TISSUE SERVICES, LTD., MEDTRONIC SOFAMOR DANEK, USA, INC.,) SPINALGRAFT TECHNOLOGIES, LLC, REGENERATION TECHNOLOGIES, INC., MICHAEL MASTROMARINO, **COMPLAINT** and JOSEPH NICELLI. **DEMAND FOR JURY TRIAL** DANIEL GEORGE & SON FUNERAL HOME. ENGLISH BROTHERS FUNERAL HOME, ABC BUSINESS ENTITIES 1-10, and JOHN DOES 1-10, Defendants.

Plaintiff Brian Collins, by way of Complaint against Defendants, states:

#### **PARTIES**

- 1. Plaintiff is a resident of lowa.
- 2. Defendant Medtronic Sofamor Danek, USA, Inc. ("Medtronic") is a

Tennessee corporation with its principal place of business at 1800 Pyramid Place.

Memphis, Tennessee 38132. Medtronic may be served on its registered agent CT Corporation System, 800 South Gay Street, Suite 2021, Knoxville, Tennessee 37929-9710.

0

٦

Ç.,

- 3. Defendant SpinalGraft Technologies, LLC ("SpinalGraft"), a subsidiary of Medtronic Sofamor Danek, Inc. Is a Tennessee corporation with its principal place of business at 4340 Swinnea Road, Suite 39, Memphis, Tennessee 38118. SpinalGraft may be served on its registered agent CT Corporation System, 800 South Gay Street, Suite 2021, Knoxville, Tennessee 37929-9710.
- 4. Defendant Regeneration Technologies, Inc. ("RTI") is a Delaware corporation with its principal place of business located at 11621 Research Circle, Alachua, Florida 32615. RTI may be served on its registered agent The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.
- 5. Defendant Biomedical Tissue Services, Ltd. ("BTS") is a New Jersey corporation with its principal place of business located at 2125 Center Avenue, Suite 300, Fort Lee, New Jersey 07024. BTS may be served on its registered agent Michael Mastromarino, 260 Columbia Avenue, Suite #1, Fort Lee, New Jersey 07024.
- 6. Defendant Michael Mastromarino ("Mastromarino") is an individual located at 8 Buckingham Road, Fort Lee, New Jersey 07024. Mastromarino may be served at that address or 260 Columbia Avenue, Suite #1, Fort Lee, New Jersey 07024.
- 7. Defendant Joseph Nicelli ("Nicelli") is an individual located at 29 Clifton Avenue, Staten Island, New York 10305-4911 and may be served at that address.
  - 8. Defendant Daniel George & Son Funeral Home ("Daniel George & Son")

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 3 of 23

is a business entity located at 1852 Bath Avenue, Brooklyn, New York 11214. Daniel George & Son may be served at that address.

- 9. English Brothers Funeral Home, Inc. ("English Brothers") is a business entity located at 2203 Avenue Z, Brooklyn, New York 11235. English Brothers may be served at that address.
- 10. Defendants ABC Business Entities 1-10 are multiple alternative and fictitious individuals and/or business entities whose names, addresses and identities are presently unknown to Plaintiff.

C

٥

11. Defendants John Does 1-10 are multiple alternative and fictitious individuals whose names, addresses and identities are presently unknown to Plaintiff.

#### **JURISDICTION AND VENUE**

12. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1332. The amount in controversy, exclusive of interest and costs, exceeds Seventy-Five Thousand and No/100 Dollars (\$75,000.00). Moreover, there is complete diversity, as Plaintiff is a citizen of lowa and no Defendant is a citizen of lowa.

#### **FACTUAL BACKGROUND**

13. Plaintiff alleges that beginning in 2002, former New Jersey dentist and oral surgeon, Mastromarino, entered into a partnership with Nicelli, a master embalmer, to open BTS for the purpose of harvesting human tissue, bone, and organs from human corpses for resale to commercial human tissue, bone, and organ processors and resellers. When human tissue, such as ligaments, tendons, heart valves, skin, or bone, are removed from one human for preparation and transplantation into another, the

tissue, bone, or organ is known as an allograft.

- 14. Plaintiff alleges that shortly after opening their business, Mastromarino and Nicelli began harvesting tissue and bones from human bodies they improperly obtained from various funeral homes, and perhaps from local city morgues in cases in which the bodies were unclaimed or unidentified.
- 15. Plaintiff alleges that Daniel George & Son and English Brothers provided corpses to Mastromarino, Nicelli and BTS.
- 16. Plaintiff alleges that the deceased individuals obtained by BTS from funeral homes and dissected by Mastromarino never intended to be tissue donors, or if they did they did not give their consent to have their tissues or bones removed with the correct authorizations, and their families never authorized the use of their bodies for human tissue harvesting or later transplantation.
- 17. Plaintiff alleges that to circumvent obtaining releases from the families of the dissected corpses, BTS, Mastromarino, Nicelli and/or their agents or employees secretly dissected the bodies and prepared them for burial without the knowledge of family members. Such dissections included replacement of harvested bone and tissue with foreign objects, such as PVC piping and other objects, so that bodies would still appear normal for their pending visitations and funerals.
- 18. Plaintiff alleges that BTS, Mastromarino, Nicelli, and/or their agents or employees also altered the medical records, death certificates, and even identities of the corpses to conceal the lifestyle and medical or disease histories of the corpses.

  Thus, they harvested and sold tissue or bone for implantation that came from persons who potentially suffered from chronic infectious diseases such as syphilis, HIV-1, HIV-2,

AIDS, or hepatitis and who died from these diseases or from cancer or heart disease.

19. Once removed, the stolen human tissue or bones were sold by BTS to certain commercial tissue processing and allograft distribution companies, including Medtronic, SpinalGraft and TRI for processing and resale throughout the United States.

۱

- 20. Plaintiff alleges that Defendant Medtronic, either directly or through its partners, affiliates, agents, or servants, holds itself out to the public as a business engaged in the sale, promotion, marketing, harvesting, testing, procurement, preservation, and distribution of products from human tissues and bones for medical use and implantation in the human body to hospitals, physicians, and surgery centers nationwide. The allografts are implanted into patients undergoing orthopedic, dental, oral maxillofacial, urinary, and cardiovascular surgeries. Medtronic promotes and markets its products to health care providers and the general public with assurances of safety, fitness, and merchantability.
- 21. Plaintiff alleges that Defendant SpinalGraft, either directly or through its partners, affiliates, agents, or servants, holds itself out to the public as a business engaged in the sale, promotion, marketing, harvesting, testing, procurement, preservation, and distribution of products from human tissues and bones for medical use and implantation in the human body to hospitals, physicians, and surgery centers nationwide. The allografts are implanted into patients undergoing orthopedic, dental, oral maxillofacial, urinary, and cardiovascular surgeries. SpinalGraft promotes and markets its products to health care providers and the general public with assurances of safety, fitness, and merchantability.
  - 22. Plaintiff alleges that Defendant RTI, either directly or through its

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 6 of 23

(

( )

partners, affiliates, agents, or servants, holds itself out to the public as a business engaged in the sale, promotion, marketing, harvesting, testing, procurement, preservation, and distribution of products from human tissues and bones for medical use and implantation in the human body to hospitals, physicians, and surgery centers nationwide. The allografts are implanted into patients undergoing orthopedic, dental, oral maxillofacial, urinary, and cardiovascular surgeries. RTI promotes and markets its products to health care providers and the general public with assurances of safety, fitness, and merchantability.

- 23. Defendants ABC Business Entities 1-10 were negligent and/or otherwise responsible in some manner for the events and happenings referred to herein and negligently or otherwise caused the injuries or damages as alleged in this Complaint.
- 24. Defendants John Does 1-10 were responsible in some manner for the events and happenings referred to herein and negligently or otherwise caused the injuries or damages as alleged in this Complaint.
- 25. Plaintiff alleges that Defendants Medtronic, SpinalGraft and RTI in acquiring tissue, bones, and organs for making allografts, are subject to their own internal procedures, based on industry standards and state and federal regulations, which require them to (1) sterilize the allografts using their own patented processes to remove viruses, bacteria, fungi, and spores, and (2) to ensure that donors and their raw human tissues and bones meet strict criteria before allografts are released for implantation by conducting stringent blood tests, medical record investigations, medical histories, coroner report analyses, lifestyle screenings to determine donor behavior and lifestyle risks, and interviews with donor's relatives or family members to confirm the

overall lifestyle of the donor and the donor's consent to tissue removal after death.

26. Plaintiff alleges that beginning in or around 2000, Mastromarino and Nicelli, doing business as BTS, illegally dissected scores of human corpses, harvesting millions of dollars worth of tissue, bone, and organs and resold all the human material to Defendant allograft processors throughout the Unites States and Canada.

٧

<u>(</u>:

- 27. Plaintiff alleges that during the same period, Defendants Medtronic, SpinalGraft and RTI, in violation of industry standards, their own internal safety and testing procedures, and possibly state and federal laws, purchased, processed into allografts, and resold for implantation substantial quantities of tissue, bone, and organs they acquired from BTS.
- 28. On October 13, 2005, the FDA advised the public of a voluntary recall of human tissue for implantation of all tissue and bone product distributed by BTS.
- 29. Plaintiff alleges that Medtronic, SpinalGraft and RTI failed to recognize or acknowledge the deficient testing, screening, or consent of the donor and the donor product, but nonetheless proceeded to permit the allograft products to enter into the stream of commerce.
- 30. On 9/4/05, Plaintiff was a patient at St. Mary's Duluth Clinic, 400 East Third Street. Duluth, MN 55805 where he underwent back surgery.
- 31. In November of 2005, Plaintiff received a letter from Dr. James
  Callahan informing the Plaintiff that the bone and tissue used in his surgery on 9/4/05
  was obtained through Defendant Biomedical Tissue Services, Ltd., and that it recently
  announced a recall for some of its bone and tissue products used as far back as 2003
  due to questions about the adequacy of proper screening.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 8 of 23

32. Although Plaintiff is emotionally distraught by having learned of his potential exposure to syphilis, HIV-1, HIV-2, AIDS, hepatitis, and/or cancer, and by having the stolen and improperly processed tissue or bone in his body, Plaintiff cannot have his allograft removed or replaced.

(

- 33. The Defendants' responsibilities to Plaintiff were non-delegable, and therefore Defendants have direct liability for the negligent, reckless, wanton or intentional acts by any person or entity under Defendants' control, direct or indirect, including its employees, agents, consultants, and independent contractors, whether inhouse or outside entities, individuals or agencies, or caused by Defendants' policies, whether written or unwritten, or common practices.
- 34. Because of the actions or omissions of the Defendants, Plaintiff was caused physical injury and shall in the future be caused damage, including but not limited to significant emotional harm, distress, and financial loss.
- 35. Plaintiff also reserves the right to claim damages for any other disease that he contracts as a result of the acts or omissions of the Defendants.

# COUNT ONE PRODUCTS LIABILITY

- 36. Plaintiff incorporates all previous paragraphs by reference as if fully set forth herein.
- 37. At all times relevant, Defendants were engaged in some manner in the business of procuring, harvesting, testing, evaluating, preserving, selling, marketing, labeling, advertising or supplying products from human tissue and bone for implantation in the human body.

- 38. At all times relevant, Defendants intended the tissue or bone product implanted in Plaintiff to be implanted in a living human body.
- 39. At all times relevant, Defendants negligently and carelessly procured, harvested, tested, researched, evaluated, preserved, supplied, marketed, labeled, advertised, supplied, sold, warned or failed to warn of the dangers associated with the subject donor tissue or bone product.
- 40. Defendants harvested, retrieved, sold, promoted, marketed, labeled, tested, procured, preserved, inspected, designed, manufactured, or distributed human tissue, human bone, human body parts, and medical products used for implantation into the human body.
- 41. Defendants reasonably expected that the human tissue, human bone, body part, and medical products used for implantation into the human body would reach an individual such as Plaintiff as the ultimate user or consumer in the condition it was in at the time of implantation.
- 42. At the time of implantation, the product implanted into Plaintiff when sold was not merchantable or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injury sustained by Plaintiff.
- 43. At the time of implantation, the product implanted into Plaintiff as set forth above was unreasonably dangerous, defective, or not reasonably fit, suitable, or safe for its intended use, and failed to perform in a manner reasonably expected in light of its nature and intended function, and the defects subjected the Plaintiff to an unreasonable risk of harm as set forth in this Complaint.
  - 44. The product described in this Complaint was defective as marketed, in

that the advertising and marketing campaigns and programs undertaken by Defendants misled consumers or their physicians as to the safety of the product and failed adequately to warn consumers or their physicians of the dangerous conditions as described in this Complaint.

0

◐

Ö

- 45. The product implanted in Plaintiff and described in this Complaint was defective in its design, in that the risks inherent in its design outweigh the utility of the product so designed.
- 46. The product described in this Complaint was fully defective in its design, manufacture, marketing, assembly, and warning because it failed to provide for a safe condition when used in the manner its was intended and was furnished without adequate warning.
- fraudulently, maliciously, or oppressively toward Plaintiff and others by compromising their safety for profit. Defendants, all or certain of them, had actual knowledge, or should have had actual knowledge, of the serious potential dangers posed to Plaintiff and others from contaminated donor tissue or bone, as well as its inadequately tested, treated, evaluated, or labeled human tissue and bone products, and that these products posed serious dangers to persons receiving them as implantations. Defendants, all or certain of them, intentionally or in a willful or conscious disregard for the safety of Plaintiff and others using their products, misled Plaintiff and health care professionals, including doctors, surgeons, and hospitals, regarding the danger posed to Plaintiff and other patients from potentially contaminated human tissue or bone so that Defendants, all or certain of them, could increase their financial profits.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 11 of 23

48. The product described in this Complaint was defective in its design, manufacture, or warnings that accompanied it.

(

0

- 49. Defendants made misrepresentations regarding the safety, sterility, and uncontaminated condition of their tissue and bone products without any reasonable grounds for believing the representations to be true.
- 50. At all times relevant, Defendants' representations were made with the intent to induce Plaintiff, Plaintiffs' health care providers, and the general public to rely on them.
- 51. At all times relevant, Plaintiff and his health care providers were unaware of the falsity or misleading nature of Defendants' representations, acted in reliance on the truth of the representations, and were justified in doing so.
- 52. Defendants' acts and omissions breached implied warranties of fitness and merchantability of the product supplied to and implanted in Plaintiff.
- 53. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff was caused physical injury, and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
- 54. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of sult, attorneys' fees, and all such other relief as the court deems proper.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 12 of 23

### COUNT TWO NEGLIGENCE

0

٥

0

- 55. Plaintiff incorporates all previous paragraphs by reference as if fully set forth herein.
- 56. At all times relevant, Defendants were engaged in some manner in the business of procuring, harvesting, testing, evaluating, preserving, selling, marketing, labeling, advertising or supplying products from human tissue and bone for implantation in the human body.
- 57. At all times relevant, Defendants intended the tissue or bone product implanted in Plaintiff to be implanted in a living human body.
- 58. At all times relevant, Defendants negligently and carelessly procured, harvested, tested, researched, evaluated, preserved, supplied, marketed, labeled, advertised, supplied, sold, warned or failed to warn of the dangers associated with the subject donor tissue or bone product.
- 59. As a direct and proximate result of the conduct of Defendants as stated above, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including but not limited to obligations for medical services and expenses, present and future lost wages, and other damages.
- 60. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all other relief as the court deems proper.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 13 of 23

## COUNT THREE NEGLIGENT MISREPRESENTATION

- 61. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 62. Defendants made the alleged misrepresentations described above regarding the safety, sterility, and uncontaminated condition of their tissue and bone products without any reasonable grounds for believing the representations to be true.
- 63. At all times relevant, Defendants' representations were made with the intent to induce Plaintiff, Plaintiffs' health care providers, and the general public to rely on them.
- 64. At all times relevant, Plaintiff and his health care providers were unaware of the falsity or misleading nature of Defendants' representations, acted in reliance on the truth of the representations, and were justified in doing so.
- 65. As a direct and proximate result of the fraudulent and misleading conduct described above, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
- 66. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 14 of 23

# COUNT FOUR INTENTIONAL MISREPRESENTATION

 $\mathbb{C}$ 

0

- 67. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 68. Defendants, all or certain of them, made numerous false, misleading, and fraudulent representations to the general public and to Plaintiffs health care providers, leading Plaintiffs health care providers, among others, to believe that Defendant's tissue and bone product was safe, sterile, and uncontaminated.
- 69. These representations by Defendants, all or certain of them, were false.

  Defendants' tissue and bone products were not safe and had dangerous and potentially life-threatening effects and consequences.
- 70. These representations by Defendants were material, in that if Plaintiff and his health care providers had known the truth, Plaintiff would not have accepted the product into his body.
- 71. The fact that the product implanted into Plaintiff was not what Defendants represented it to be was susceptible of knowledge.
- 72. Defendants, all or certain of them, made these representations knowing them to be false and misleading, and with the intent to defraud, mislead, and deceive Plaintiff's health care providers, and with the intent to induce Plaintiff's health care providers, Plaintiff, and the general public, to use Defendants' products.
- 73. Plaintiff, Plaintiff's health care providers, and the general public, used
  Defendants' products. If Plaintiff and Plaintiff's health care providers had known the
  truth about the facts and dangers posed by Defendants' products, they would not have

Case 3:06-cy-03072-MWB Document 2-1 Filed 11/03/2006 Page 15 of 23

used Defendants' products.

(

(

( .

- 74. Plaintiff and the health care providers acted in reliance on Defendants' misrepresentations.
- 75. As a direct and proximate result of the fraudulent and misleading conduct described herein, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
- 76. In performing the described acts or omissions, Defendants, all or certain of them, acted fraudulently, maliciously, or oppressively toward Plaintiff and others by compromising their safety for the benefit of profit. Defendants, all or certain of them, had actual knowledge, or should have had actual knowledge, of the serious dangers posed to Plaintiff and others from contaminated donor tissue or bone, as well as inadequately tested, treated, evaluated, or labeled human tissue and bone products, and that these products posed serious danger to persons receiving them. Defendants, all or certain of them, intentionally or in a willful or conscious disregard for the safety of Plaintiff and others using its products, misled Plaintiff and health care professionals, including doctors, surgeons, and hospitals, regarding the danger posed to Plaintiff and other patients from contaminated human tissue or bone so that Defendants, all or certain of them, could increase their financial profits.
- 77. As a direct and proximate result of Defendants' misrepresentations,
  Plaintiff was caused physical injury and shall in the future be caused to suffer severe
  personal injuries, pain and suffering, severe emotional distress and harm, financial or

economic loss, including but not limited to obligations for medical services and expenses, present and future lost wages, and other damages.

78. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

#### COUNT FIVE EXPRESS WARRANTY

- 79. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 80. Defendants placed the bone and tissue product that is the subject of this Complaint into the stream of commerce for sale and recommended its use to physicians, surgeons, and consumers without adequately warning physicians, surgeons, the FDA, and consumers, including the Plaintiff, of the risks associated with its use.
- 81. Defendants had a duty to exercise reasonable care in the harvesting, retrieving, selling, promoting, marketing, labeling, testing, procuring, preserving, inspecting, designing, manufacturing, or distributing human tissue, human bone, body parts, and medical products used for implantation into the human body, including a duty to:
  - ensure that the product did not cause the user unreasonably dangerous consequences;
  - (b) warn of dangerous and potentially fatal risks; and
  - (c) disclose adverse material facts when making representations to

Case 3:06-cy-03072-MWB Document 2-1 Filed 11/03/2006 Page 17 of 23

physicians, the FDA, and the public at large, including Plaintiff.

- 82. When Plaintiff's physician advised Plaintiff of the possibility of using the product at issue, both Plaintiff and his physicians reasonably relied on the Defendants and their agents to disclose known defects, risks, and dangers, as well as to advise of potentially defective manners of harvesting, retrieving, selling, promoting, marketing, labeling, testing, procuring, preserving, inspecting, designing, manufacturing, or distributing the product at issue.
- 83. Plaintiff's physicians, the FDA, or Plaintiff had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the product at issue. Plaintiff justifiably and detrimentally relied on the warranties and representations of Defendants regarding the product at issue.
- 84. Defendants were under a duty to disclose the defective and unsafe nature of the product at issue to physicians, the FDA, consumers, and users, such as Plaintiff. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA, and users, such as Plaintiff, could not reasonably have discovered such defects.
- 85. By their acts and omissions, Defendants, their agents and employees expressly warranted to Plaintiff and Plaintiff's physicians that the products were merchantable and fit for the purpose intended.
- 86. This warranty was breached because the product at issue was not safe and effective as Defendants had represented, and Plaintiff was injured.

87. As a direct result of Defendants' acts and omissions, as described herein,
Plaintiff was caused physical injury and shall in the future be caused to suffer severe

0

**(**)

٠

personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

88. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

#### COUNT SIX PUNITIVE DAMAGES

- 89. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 90. The Plaintiff is entitled to punitive damages because the Defendants' failure to warn was reckless and demonstrated willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences. The Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety of the product at issue and acting in an intentional manner with malice or a wanton and willful disregard for the rights and safety of others.
- 91. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
  - 92. Wherefore, Plaintiff demands judgment against Defendants for such sums

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 19 of 23

.

in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

# COUNT SEVEN INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

- 93. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 94. Defendants' acts and omissions demonstrated conduct that can be deemed extreme, outrageous, and unnecessarily reckless, in a deliberate intent to cause Plaintiff significant emotional distress, or that can be deemed to be a willful and wanton disregard of the fact that such emotional distress could and should be expected.
- 95. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
- 96. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

# COUNT EIGHT NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

97. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 20 of 23

98. Defendants' acts and omissions demonstrated conduct that was negligent, and this negligence caused Plaintiff severe emotional distress, given the nature of the harm caused as described in this Complaint.

- 99. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.
- 100. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

## COUNT NINE RESPONDENT SUPERIOR

- 101. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 102. At all relevant times, Mastromarino, Nicelli and John Does 1-10 were employees, agents, or servants of BTS, Medtronic, SpinalGraft, RTI, Daniel George & Son, English Brothers and/or ABC Business Entities 1-10.
- 103. The business entity or corporate Defendants are responsible or vicariously liable for the negligence, acts, and omissions of their agents, employees, and servants based on the theory of respondent superior.
- 104. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff was caused physical injury and shall in the future be caused to suffer severe

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 21 of 23

personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

105. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

#### COUNT TEN MEDICAL MONITORING

- 106. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 107. As a result of Defendants' negligence, Plaintiff was exposed to the hazards of receiving human body parts through transplant surgery that were infected with diseases.
- 108. This exposure was greater than normal because the transplanted body parts were not tested for infectious diseases.
- 109. As a direct and proximate result of receiving the illegally obtained human body parts, plaintiff may be at risk for developing serious latent diseases because of the transplant material.
  - 110. Monitoring procedures exist that can provide early detection of disease.
- 111. The prescribed monitoring regime is different from that normally recommended in the absence of such exposure.
- 112. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

113. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for the costs of medical monitoring, compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

## COUNT ELEVEN JOHN DOES

- 114. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.
- 115. Plaintiff alleges than an insufficient amount of time has passed within which to determine the identity of any other individuals or business entities that may be responsible for causing the injuries suffered by Plaintiff.
- 116. For the purposes of this Complaint, these individuals or business entities have been nominated as ABC Business Entities 1-10 and John Does 1-10.
- 117. Plaintiff, pursuant to the Federal Rules of Civil Procedure, reserves the right to amend the Complaint to add additional Defendants when and if their identities become known.
- 118. Wherefore, Plaintiff demands judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

## COUNT TWELVE JOINT AND SEVERAL LIABILITY

119. Plaintiff incorporates the previous paragraphs by reference as though fully set forth herein.

Case 3:06-cv-03072-MWB Document 2-1 Filed 11/03/2006 Page 23 of 23

120. Wherefore, Plaintiff demands judgment against Defendants, jointly and severally, for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

#### **DEMAND FOR JURY TRIAL**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, demand is hereby made for trial by jury on all issues raised by these pleadings.

Respectfully submitted,

DUTTON, BRAUN, STAACK & HELLMAN, P.L.C. Attorneys for Plaintiffs

BY:

James H. Cook, AT0001622 3151 Brockway Road

**-₽:**Ó. Box 810

Waterloo, Iowa 50704

(319) 234-4471

(319) 234-8029 -Fax

E-Mail: cooki@wloolaw.com

I:\Lit\BlomedicafTissueSvcs\Collins\Pleadings\Complaint.wpd

(